PRESS RELEASE

Transgene and BioInvent's Armed Oncolytic Virus BT-001 Shows Positive Local, Abscopal, and Sustained Antitumoral Activity in Advanced Refractory Tumors

BT-001 in combination with pembrolizumab is well tolerated and shows sustained antitumoral activity in both injected and non-injected lesions

Data support further development of BT-001 in solid tumors to improve response to cancer immunotherapy

Strasbourg, France, and Lund, Sweden, October 20, 2025, 08:30 a.m. CEST – **Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer,** and **BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV),** a biotech company focused on the discovery and development of novel and first-in-class antibodies for cancer immunotherapy, **jointly presented a poster** at the 2025 European Society for Medical Oncology (ESMO) Annual Meeting **on updated clinical results and positive antitumoral activity of BT-001 in patients with advanced refractory tumors.**

The data show that intra-tumoral (IT) **BT-001** injection in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) intravenous (IV) anti-PD-1 therapy KEYTRUDA® (pembrolizumab*), was **well tolerated and showed positive local, abscopal and sustained antitumoral activity in injected and non-injected lesions.**

Translational analyses reveal **increased T cell chemoattractants in the blood and infiltration of activated CD8+ T cells and macrophages in tumors** after treatment with BT-001 in combination with pembrolizumab. Significant tumor shrinkage (≥30% decrease in longest diameter) was observed in five of 16 injected lesions (in three patients with melanoma and one patient with sarcoma). Four patients had **tumor shrinkage of non-injected lesions.**

Long-lasting partial responses (PRs) were observed in a patient with melanoma resistant to anti-PD-1/anti-CTLA-4 combination therapy and in a heavily pre-treated, PD-L1 negative leiomyosarcoma patient.

These immune-mediated tumor shrinkages are consistent with the mechanistic hypothesis that BT-001, in combination with pembrolizumab, turns "cold" tumors into immunologically active ones. The overall data support further development of BT-001 across a range of solid tumors to improve responses to cancer immunotherapies.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Prof. Celeste Lebbé, Dermatologist and Venereologist, Head of Dermatology Department at Hospital Saint-Louis, Paris, commented: "*Many cancer patients fail to respond to existing treatments, emphasizing the urgent need for new approaches. BT-001 represents a promising new class of immunotherapy, capable of inducing a potent local immune response through the expression of GM-CSF and an anti-CTLA-4 antibody. These clinical data provide compelling proof of concept, highlighting the relevance of this oncolytic virus in transforming cold tumors into immunologically active ones. Whether administered alone or in combination with pembrolizumab, BT-001 offers the potential to expand treatment options with a favorable safety profile across multiple tumor types*."

Dr. Alessandro Riva, Chairman and CEO of Transgene, said: *"We are pleased to jointly present these clinical data on BT-001 at ESMO 2025, demonstrating encouraging antitumor activity in patients with solid, refractory solid tumors. These updated results confirm BT-001's mechanism of action as a single agent administered via intra-tumoral injection and show early signs of clinical benefit, including lesion shrinkage and stable disease. With a favorable safety profile - both alone and in combination with pembrolizumab - BT-001 could represent an effective option to enhance responses to immune checkpoint inhibitors (ICI) in patients with limited treatment alternatives. Together with our partner BioInvent, we will continue to explore its safety and efficacy and share further data as it becomes available."*

Andres McAllister, MD, PhD, Chief Medical Officer at BioInvent, added: *"By combining BT-001 with pembrolizumab, we are building upon the promising data generated by BT-001 as a single agent. Targeting the PD-1/PD-L1 pathway in addition to BT-001's mechanism of action is expected to further stimulate and restore the patient's immune system, which should result in improved antitumoral activity and patient outcome. We are pleased to pursue clinical development opportunities with clinicians and further demonstrate the potential of this novel oncolytic virus."*

Transgene and BioInvent are co-developing BT-001, an oncolytic virus developed using Transgene's Invir.IO® platform armed to express GM-CSF and BioInvent's full-length anti-CTLA-4 monoclonal antibody, to elicit a strong and effective anti-tumoral response in solid tumors.

The poster titled: "Updated clinical results of BT-001, an oncolytic virus expressing an anti-CTLA4 mAb, administered in combination with pembrolizumab in patients with advanced solid tumors.", can be accessed at the websites for the ESMO conference, Transgene and BioInvent.

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About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. TG4050, the first individualized therapeutic vaccine based on the *myvac®* platform is the Company's lead asset, with demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers. The Company has other viral vector-based assets, including BT-001, an oncolytic virus based on the Invir. IO® viral backbone, which is in clinical development. The Company also conducts innovative discovery and preclinical work, aimed at developing novel viral vector-based modalities.

With Transgene's *myvac®* platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The *myvac®* approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.

With its proprietary platform Invir.IO®, Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses.

Additional information about Transgene is available at: www.transgene.com

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About BT-001

BT-001 is an oncolytic virus, from Transgene's invir.IO® platform, with enhanced replication selectivity in tumor cells and recombinantly armed to express an anti-CTLA4 antibody generated by BioInvent's proprietary n-CoDeR®/F.I.R.S.T™ platforms, and the human GM-CSF cytokine. By selectively targeting the tumor microenvironment, BT-001 is designed to induce a strong and effective anti-tumor response and by limiting systemic exposure, this approach aims to significantly improve the safety and tolerability profile of the human anti-CTLA-4 antibody. The ongoing Phase I/IIa trial (NCT04725331) is a multi-center, open-label study, and aims to evaluate safety and antitumor activity of intratumoral BT-001 alone and in combination with pembrolizumab in patients with advanced solid tumors.

About BioInvent

BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical-stage biotech company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with several drug candidates in ongoing clinical programs in Phase 1/2 studies for the treatment of hematological cancer and solid tumors, respectively. The Company's validated, proprietary F.I.R.S.T.™ technology platform identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline and providing licensing and partnering opportunities.

The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit. More information is available at www.bioinvent.com

Disclaimer Transgene

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Universal Registration Document, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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